C. Remarks

The claims are 1 and 3-16, with claims 1, 12 and 15 being in independent form. Claims 5-8 and 10-14 have been withdrawn from consideration. New claims 15 and 16 have been added to provide Applicant with a more complete scope of protection. Support for the new claims may be found, for example, in Example 7 on page 19 of the specification. No new matter has been added. Favorable reconsideration is requested.

Claims 1, 3, 4, and 9 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over WO 01/12161 ("Martani") in view of S.T.P. Pharma Sciences 11 (3) 211-220, 2001 ("Mattsson"). The grounds of rejection are respectfully traversed.

As acknowledged by the Examiner, Martani does not teach at least the claimed particle sizes of the active ingredient and microcrystalline cellulose and the friability value of the tablet. In fact, Martani's disclosure of 30% microcrystalline cellulose ("filler") teaches away from the present claims, which recite that the tablet contains 10-18% microcrystalline cellulose. See Martani, page 11, third full paragraph. In addition, Martani does not disclose or suggest the use of spray-dried mannitol.

Mattsson does not remedy the deficiencies of Martani. Mattsson discloses rapidly disintegrating tablets comprising a compound such as sodium chloride, a binder such as microcrystalline cellulose and a superdisintegrant such as carboxy methyl cellulose sodium. Mattson does not disclose or suggest spray-dried mannitol, microcrystalline cellulose with a particle size of approximately 50 μm or the friability value of the tablet.

The Examiner has alleged that the present specification states that Pearlitol®mannitol is spray-dried mannitol. The Examiner then concludes that since Pearlitol®mannitol is available in granulated form and Mattson discloses the use of

granulated mannitol, Mattson meets the limitation of presently claimed spray-dried mannitol. This conclusion is incorrect. In fact, the opposite is the case here.

As mentioned previously by Applicant, Pearlitol®mannitol is available in two distinct forms - spray-dried and granulated. While Mattson refers only to one of these forms, granulated, the present claims recite another, spray-dried mannitol, which is made up fundamentally by the crystalline form. Thus, Mattson does not teach or suggest the use of spray-dried mannitol as presently claimed.

Spray-dried mannitol helps to produce a tablet with a friability below 0.5% as evidenced from Tables IV and V of the present specification. As shown in these tables, the friability of the tablet is outside the claimed range of below 0.5% (see Example 5) when direct compression dextrose is used in the place of spray-dried mannitol of the other Examples in these tables.

In addition, neither Martani nor Mattson recognizes the importance of the particle size of the active ingredient. According to the Examiner, the disclosure in Table I of Mattson of "90-180" μm DCP satisfies the claimed particle size requirement of the active ingredient. However, clearly there is no recognition of the importance of the particle size being less than 100 μm or disclosure as to what proportion of the particles in Mattson are between 90 and 100 μm. In fact, a predominant amount of the particles may be closer to 180 μm than to 100 μm. The Examiner has asserted that the criticality of the claimed particle size of the active ingredient has not been shown. Applicant respectfully disagrees.

The particle size of the active ingredient as recited in the claims plays a significant role in producing a tablet that is palatable. As mentioned in the specification at page 7, lines 21-25, "to guarantee the palatability of the finished product and the uniformity of the

mixture, the active ingredient must be a fine powder, where at least 90% in weight of the active ingredient has a particle size of below 100 μm."

In fact, it has been observed that when active ingredient with particle size greater than 100 μm was used, the resulting tablet had a gritty mouthfeel, which is undesirable for ordodispersible tablets. Thus, the claimed particle size of the active ingredient provides unexpected results, which is neither recognized nor suggested in the cited art.

Similarly, the claimed microcrystalline cellulose particle size and its proportion in the tablet make it "possible to significantly improve compressibility, reduce friability and achieve a substantial reduction in disintegration time. Higher quantities have a negative impact on the palatability of the formula and lower quantities worsen the capacity of the disintegration promoter." (Page 8, lines 2-8). Thus, the particle sizes and their proportion as claimed provide the tablet with advantageous properties. It is clear that these parameters are not the result of routine optimization.

Wherefore, Applicant respectfully submits that none of the references of record, whether taken alone or together, describes or suggests the present claims 1, 3, 4, 9, 15 and 16. New claims 15 and 16 are also patentable because they claim a tablet for oral administration with a specific active ingredient and excipients in specified amounts and with specified particle sizes of the components. Accordingly, it is respectfully requested that the claims be allowed and are passed to issue.

In view of the foregoing amendments and remarks, Applicant respectfully requests favorable reconsideration and early passage to issue of the present application. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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